ANVISA
Brazilian Health Regulatory Agency

EXECUTIVE SUMMARY

MANAGEMENT REPORT 2024
BRAZILIAN HEALTH REGULATORY AGENCY

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For more detailed information, see the full 2024 Management Report, available on Anvisa's website: **https://www.gov.br/anvisa/pt-br/centraisdeconteudo/publicacoes/gestao/relatorios-de-gestao**

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Planning Office

Gustavo Henrique Trindade da Silva

Communication Office

Átila Regina de Oliveira

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ANVISA

The Brazilian Health Regulatory Agency (Anvisa) is a regulatory agency linked to the Ministry of Health (MS). It was created 1999 as an autarchy under a special regime, with headquarters and jurisdiction in the Federal District (DF) whose operations comprise the whole Brazilian territory.

MISSION: To promote and protect the health of the Brazilian population, acting with scientific excellence in the regulation of products, services and environments subject to health surveillance, promoting access, reducing risks and supporting the development of the country in an integrated action with the Brazilian Unified Health System.

VISION: To be an innovative and reliable health authority for the entire society.

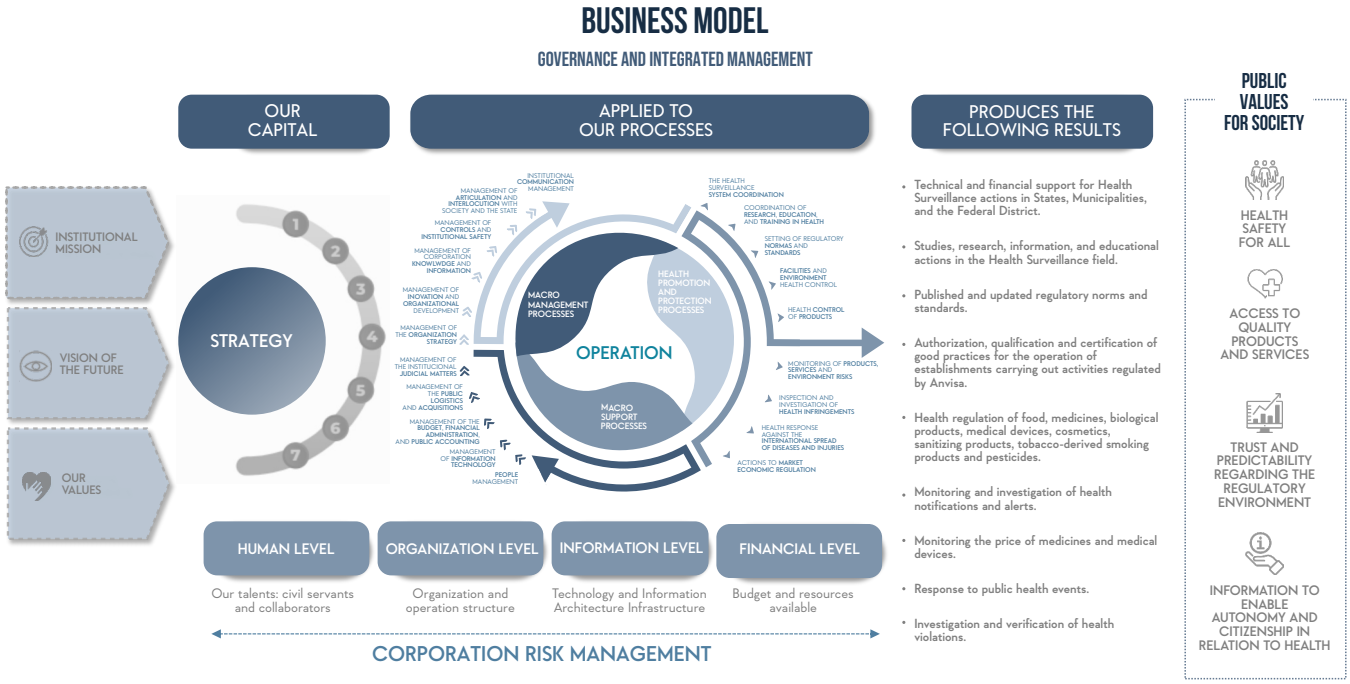
VALUES: A systemic vision, integrated with the Brazilian Unified Health System; Transparency, communication and integrity; Knowledge as a source of action; Excellence in service provision; Innovation and Sustainability.

Business Model

Anvisa adopts an integrated governance and management model, which includes a strategic dimension and an operational dimension. Our strategy map reflects the main priorities for the 2024-2027 cycle, based on the Agency's mission and vision for the future. Our value chain systematizes the organizational processes which have been established to fulfill Anvisa's legal attributions.

This document is a summary of the main results and renderings provided in 2024. For more information, we suggest checking the full Management Report, available on Anvisa's website.

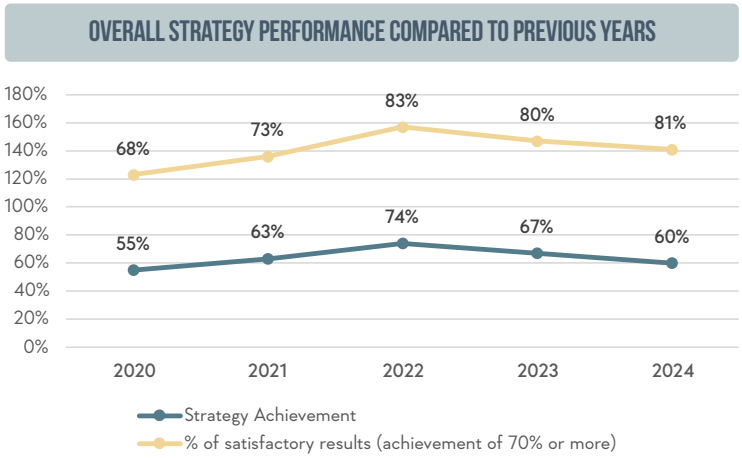
LINK



Strategy Achievement in 2024

Strategic Planning (SP) 2024-2027: 28 Key Results (KRs)

Annual Management Plan (AMP) 2024: 24 KRs



International Position

Strategic Project: Anvisa was acknowledged as an international health authority reference by the World Health Organization (WHO Listed Authority)

Actions in 2024:

- Formal application for candidacy and signing the work plan with the Pan American Health Organization (PAHO) and the World Health Organization (WHO);

- Provision of information and evidence related to the sub-indicators required by the Global Benchmarking Tool (GBT);

- 18 meetings with the PAHO and WHO audit team, explaining Anvisa's regulatory functions.

Trade Agreements:

- Signing the Brazil-Chile Trade Initiative for Cosmetics.

- Participation in the chapters on technical barriers to trade and sanitary and phytosanitary measures of the Mercosur and the United Arab Emirates trade agreement.

- Global agreement on plastic pollution: the United Nations Environment Program kept negotiations to reduce plastic pollution.

MANAGEMENT RESULTS

Pesticides

Changes to the Pesticides Regulatory Framework

In 2024, due to Law No. 14,785/2023, which changed the legal framework concerning pesticides and established a period of transition (360 days), Anvisa conducted a survey of its standards and procedures and concluded that many of these norms required adjustments. Therefore, the agency carried out a series of discussions on the subject, resulting in the proposal of a regulatory decree to the Civil House/ Brazil Presidency and to the Ministry of Health.

Toxicological analysis of pesticides

To speed up the analysis of equivalent products, Anvisa published in December 2024 Resolution No. 950. The act aims to reduce the queue of requests, which, in 2024, reached 2,200 processes, of which 50% would be suitable for an optimized analysis. With the implementation of this Resolution, we expect a reduction in the judicialization related to analysis requests and to work faster, since the number of toxicological evaluation requests historically exceeds the number of petitions effectively analyzed.

LINK

Preparation, update or exclusion of monographs of pesticides active ingredients, and their components

In 2024, 25 Normative Instructions were published, containing:

Coordination of national monitoring networks and programs

The Analysis Program of Pesticide Residue in Food (PARA - acronym in Portuguese) is a strategic tool for Anvisa, essential to ensure food safety in Brazil, since it assesses the presence of pesticide residues in/on food. In 2024, the results of the previous year were published. The program monitored 14 types of food: 3,294 samples were collected and analyzed nationwide, as part of the 2023-2025 Multi-Year Plan. According to the results, 22 samples (0.67%) showed potential acute risk (short-term exposure).

Regarding the risks of daily exposure throughout life, no situation with potential risk was found, if we consider the data collected during the last 10 years. Regarding the MRL (Maximun Residue Level), 73.9% of the samples were within the limit, 37% with no residues detected, and 26.1% contained non-conformities, which include residues above the MRL or pesticides not authorized for a specific crop or prohibited in the country. For the 2024 cycle, more than 3,000 samples of 14 foods were collected in 26 States.

Compliance with the deadline for publishing the *PARA Annual Cycle Report*:

PUBLISHED IN THE EXPECTED DEADLINE

Percentage of samples collected in relation to the total samples planned for the period:

3,226 registered samples/ 3,573 planned

Food

Food and beverages regularization

The year 2024 began with a new legal framework for the regularization of food and packaging, following the enactment of RDC 843 and Normative Instruction (IN) 281. The rules were published in February and came into force in September 2024. Registration was restricted to eight categories of food consumed by vulnerable groups and those with very specific nutritional needs, including diet therapy formulas for inborn metabolism problems. Six categories of food were exempted from this obligation and will now be notified to Anvisa. Dietary supplements and weight loss foods, previously regularized with local health authorities, will also be notified.

Risk and efficacy assessment

Anvisa significantly reduced the time related to waiting list, analysis and completion of risk and efficacy assessment petitions over 5 years. This was done without changes to the technical foundations. In 2024, the completion time was reduced to almost half in relation to the beginning of the historical series.

However, the evaluation of new foods and ingredients took a bit longer: an increase of 51 days compared to 2023, the year with the shortest time in the last 5 years. This was due to the concentration of the technical team on implementing the new regulatory framework for the safety evaluation of new foods and ingredients, which was approved by Resolution RDC 839/2023. We expect the new rules are going to improve clarity on instruction and classification requirements for foods and ingredients, as well as increase transparency in decisions, with public opinions and specification lists available to the public.

Regulatory standards and norms

Food standards and regulations cover 33 topics, corresponding to 19% of the 2024-2025 Regulatory Agenda. In 2024, 45% of the actions planned for the two-year period were completed, resulting in the enactment of 23 regulations, 16 of which were related to constant update.

Nutrivigilance

The number of notifications almost tripled compared to 2022 (43) and doubled compared to 2023 (65). A single food for special purposes, consumed by vulnerable groups, was responsible for more than half of the notifications received, requiring several health actions.

National monitoring programs

Anvisa published several reports on monitoring sodium and sugar levels in prioritized categories of processed foods that were included in the voluntary agreement of the National Sodium and Sugar Reduction Plans.

Sentinel Network

• The new Sentinels in Action platform, that works within the scope of the Community Collaboration Networks by the National Education and Research Network was launched in April. Biweekly webinars are available to the public, with speakers from collaborating institutions and Anvisa professionals. The sessions are recorded, and certificates are issued to participants. In total, 17 virtual seminars were held. All videos are available on the Sentinels in Action webpage.

• Anvisa organized the Sentinel Network Conference, with more than 600 participants, including professionals from Sentinel Network institutions, Health Surveillance agencies, Anvisa, and other relevant institutions.

• In 2024, two Sentinel Network Bulletins were published, updating topics related to the theme.

Health violations

11 investigative inspections were carried out on food

148 measures were published regarding investigation dossiers on food

335 food dossiers were carried out: 24 were concluded in 2024 and 362 have been concluded in total

Epinet Pilot Project (Targeted to the exclusion of irregular products from the internet)

Anvisa expanded the use of artificial intelligence to monitor irregular products sold on the internet.

EPINET overall results from 2021 to 2024:

EPINET GENERAL DATA – DEC/2021 TO 12/31/2024		
Signals captured	Potential threats	Notifications (takedown requests)
+ 128.000.000	+ 920.000	+ 229.633

Facilities, products and services in Ports, Airports, Borders and Customs Areas

Operating authorization or special authorization

• **1,281 petitions** regarding Company Operating Authorization in Ports, Airports, Borders and Customs Areas.

• **685 Company Operating Authorization petitions** were cancelled due to expiration dates or because the companies were closed.

Sanitary control of customs areas

• **26 customs warehouses** were inspected for compliance with Good Storage Practices.

Epidemiological surveillance in Ports, Airports, Borders and Customs Areas

34
Entry points

underwent Voluntary External Assessment. Those entry points were designated by WHO, under the terms of the International Health Regulations (IHR).

444,895
ICVP issued

International Certificates of Vaccination or Prophylaxis (ICVP) issued:

382,608 WERE NEW CERTIFICATES

62,287 WERE DUPLICATES

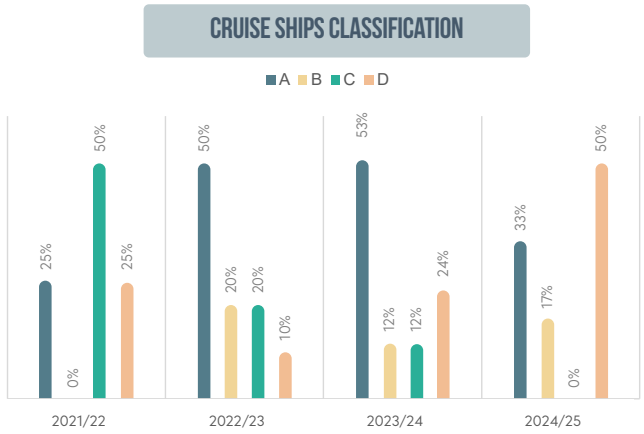
Health control of aircraft and airports

- **1 internationalization request** approved.

Health control of vessels and ports

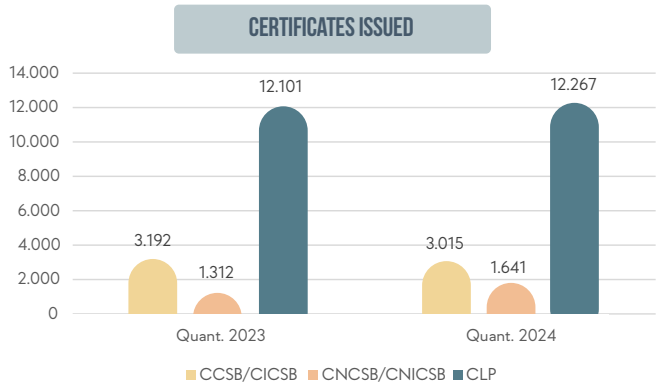
- **13 inspected vessels.**

The vessels are inspected, evaluated, and classified according to their sanitary conditions into four standards (from A to D). Standard "A" is considered excellent, while "D" indicates unsatisfactory sanitary conditions.



Non-bureaucratic Port

The Non-bureaucratic Port improvement process brought innovation to inspections scheduling. Teams were optimized, the time spent on carrying out analyses was reduced, and time and resources were saved for the regulated sector. When comparing the figures for 2023 and 2024, there was a 2% growth in the total number of certificates issued.



Authorization for exportation and importation

15% increase in the number of import processes compared to 2023:

59,889 Import Licenses

Maintenance of the 9.5-day deadline for completion of the analysis despite the increase in the number of processes.

The Authorized Economic Operator Program is one of the trade facilitation tools, established in the commitments of the Trade Facilitation Agreement of the World Trade Organization (WTO). Its goal is to provide international trade flow with agility, predictability and confidence.

17 companies in different certification categories (Certified Operators) were certified.

Cosmetics

Certification of Good Manufacturing Practices

05 inspections were conducted in the Cosmetics category out of a total of 87 inspections in the national territory.

33 requests were received to apply for the national Good Manufacturing Practices Certificate on cosmetics:

- **21** APPROVED
- **12** REJECTED

Operating authorization or special authorization

There was a great number of Operating Authorization or Special Authorization petitions received in 2024, according to Resolution RDC 16/2014, for companies that carry out activities of manufacturing, importing, exporting, distributing, storing, packaging and transporting cosmetics.
Those requests resulted in:

2,213 APPROVALS, of which:

- **1,156** were granted
- **1,000** were changed
- **57** were cancelled

Regularization of Products Under Health Surveillance

Cosmetics registration

1,076 Cosmetic registration petitions received

890 Completed

68.4% increase in protocols carried out in 2024, comparing to 2023.

Cosmetics post-registration

773 Cosmetic post-registration petitions received

576 Completed

76.9% increase in protocols carried out in 2024, comparing to 2023.

Cosmetics that are free from registration

- **71,271 new notifications** received and **1,538 processes** evaluated by the Registration Exemption Verification Program.

HIGHLIGHT

Insect repellent - action to combat arboviruses

Prioritization of registration and post-registration petitions in the "insect repellent" category, to make the products available to the population. The repellents prevent infection by Aedes aegypti and other vectors.

- 130 petitions registered and 106 completed by December 2024
- 88 post-registration petitions requested and 71 completed

Cosmetic surveillance

In 2024, **211 adverse event notifications** were recorded, of which 46.4% involved eye poisoning associated with hair styling products.

Investigation of health violations

02 investigative inspections in 2024

168 measures published regarding investigation dossiers

262 cosmetic dossiers opened, with 32 completed only from 2024 and 268 completed considering 2024 plus previous years

Sanitary Administrative Proceedings

102 Sanitary Administrative Proceedings

92 responsible parties were charged, totaling 22% of violation notices issued for cosmetics

129 health violations identified

Medical Devices

Operating authorization or special authorization

4,842 APPROVALS: 2,255 concessions; 2,408 amendments; 179 cancellations

486 REJECTIONS: 299 concessions; 187 amendments

Certification of Good Manufacturing Practices

CGMP requests received:

CGMP Requests	National level	International level
Approved	157	1260
Rejected	01	33

17 National inspections **153** International inspections

Regularization of products under health surveillance

Number of medical devices registered and notified:

Orthopedic Implants	Notifications	NA*	In-vitro Diagnostic Devices	Notifications	1034
	Records	194		Records	506
Healthcare Materials	Notifications	4723	Equipments	Notifications	1247
	Records	250		Records	387

TOTAL = **8341**

Authorization, modification or cancellation of clinical research

Anvisa analyzed 61% of requests for approval of clinical research on medical devices within the ideal timeframe, exceeding the annual target of 49% established in the Agency's OKR (Objectives and Key Results) program.

CLINICAL RESEARCH APPROVALS OF MEDICAL DEVICES IN 2024

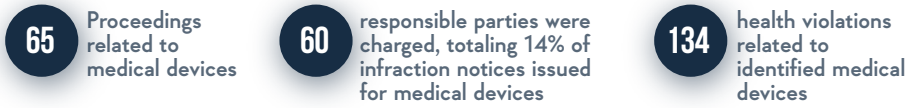
Actions of the health surveillance notification and investigation system

Health inspection

- **15 investigative inspections** and **support inspections** to state Health Surveillance Organs/Agencies.

Health violations investigation

Health Administrative Proceeding



Analytical Laboratories

Network of Analytical Laboratories in Health

Regulatory data on products under health surveillance

- **586 processes** from official public and accredited laboratories requesting information on regularized products.

Brazilian Pharmacopoeia

Publication of the 7th edition of the Brazilian Pharmacopoeia and the 3rd edition of the Homeopathic List.

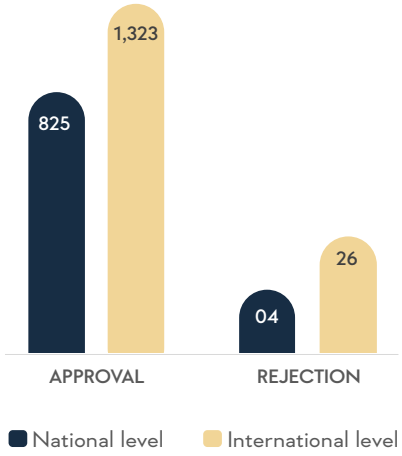
These publications contain the general methods that have been harmonized with international requirements, as well as the monographs of the monocyte activation test and Cannabis sativa inflorescence.

Medicines and Pharmaceutical Supplies

Good Manufacturing Practices Certification

Number of inspections performed:

Number of CGMP requests:



Certification of Good Distribution and Storage Practices

- **58 Certification of Good Distribution and Storage Practices** for medicines and 2 for approved pharmaceutical ingredients.

Qualification and certification of research centers

Regularization of products under health surveillance

Publication of **283 decisions** regarding applications for registration of generic, similar, new, innovative, specific, phytotherapeutic and dynamized drugs, including applications for health authorization for Cannabis products.

Registration

The number of applications for registering generic, similar, new, innovative, specific, herbal and dynamized drugs was close to the record reached in 2023. This situation shows a possible opportunity to increase the Brazilian population's access to drugs in many categories. However, it requires an even greater challenge for Anvisa to meet demands and legal deadlines.

Regulatory agenda

There has been a significant progress in the regulatory scenario regarding drugs, with the enactment of several regulations and guidelines published by Anvisa.

NORM	DESCRIPTION
RESOLUTION RDC NO. 851/2024	Amends Resolution RDC No. 73/2016, which provides for post-registration changes, cancellation of registration of drugs with synthetic and semi-synthetic active ingredients and other provisions.
RESOLUTION RDC NO. 870/2024	Provides for notification, registration and post-registration changes of medicinal gases classified as drugs.
RESOLUTION RDC NO. 882/2024	Provides for the criteria and procedures for classifying drugs as non-prescription drugs and reclassifying them as prescription drugs.
RESOLUTION RDC NO. 885/2024	Provides for a pilot project with transitional guidelines for implementing the digital package insert, allowing for the optional dispensing of the printed package insert on drug packaging, with a guarantee of its provision upon request by the healthcare facility, the prescribing professional or the patient.
RESOLUTION RDC NO. 941/2024	Provides for the validation of bioanalytical methods and analysis of study samples for regulatory submissions of manufactured drugs for human use.
RESOLUTION RDC NO. 954/2024	Provides for the simplified procedure for requests for registration, post-registration and renewal of drug registration and other provisions.
RESOLUTION RDC NO. 957/2024	Provides for the criteria for indicating a drug as a reference drug, the procedures for including and excluding drugs from the List of Reference Drugs.
RESOLUTION IN NO. 327/2024	Provides for the need of pharmacodynamic study to prove the bioequivalence of topical dermatological corticosteroids, under the terms of Resolution RDC No. 742, of August 10, 2022.
NORM INSTRUCTION IN NO. 328/2024	Provides for bioequivalence studies for transdermal patches containing rivastigmine, under the terms of Resolution RDC No. 742, of August 10, 2022.
NORM INSTRUCTION IN NO. 301/2024	Sets out the list of medicinal gases classified as drugs subject to notification.
NORM INSTRUCTION IN NO. 329/2024	Approves the List of administration methods and analytes to be quantified in relative bioavailability/ bioequivalence studies and pharmacokinetic studies for immediate-release pharmaceutical forms.
NORM INSTRUCTION IN NO. 337/2024	Amends Norm Instruction IN No. 258/2023, which defines the List of qualified impurities and their respective limits.
GUIDE NO. 72/2024	Guide for validation of bioanalytical methods and analysis of study samples for regulatory submissions of industrialized drugs for human use", referring to the implementation of "*ICH M10 - BIOANALYTICAL METHOD VALIDATION AND STUDY, SAMPLE ANALYSIS*".

Health control of medicines, plants, fungi and substances under special control

Enactment of Resolution RDC No. 873/2024, which implements the National Prescription Control System, a management system for distributing the numbering of Prescription Notifications by local Health Surveillance Authorities.

Cannabis-derived products

- **167,337 authorizations** for the import of Cannabis-derived products.

Consent, suspension and other decisions regarding clinical research of medicines and biological products

315 petitions were received for approval of clinical trials

262 of which,were evaluated

Monitoring of the drug market

- **739 complaints** related to violations in sales to the government, Maximum Sales Price to the Government were analyzed

- **77 complaints** about violations in sales in the private market were analyzed

- **1,150 administrative sanctioning proceedings** were opened, with **385 decisions** (374 convictions and 11 acquittals)

Actions of the Health Surveillance Notification and Investigation System (VIGIPOS)

Since 2021, the country has exceeded the WHO target of 200 notifications per million inhabitants, thanks to the growth in notifications, mainly by pharmacists.

269 Total number of suspected Adverse Drug Reactions notifications per 1,000,000 inhabitants/year

In 2024, 14 inspections were carried out to assess the pharmacovigilance systems of the Drug Registration Holders.

Assessment of the risk of shortages or restrictions on access to the drug market

• **345 Technical Notes** were published, to analyze the possibility of drug shortages on the market. This information is relevant to the Ministry of Health, health departments, other health services and the regulated sector, as it guides actions aimed at minimizing impacts on the population.

Health inspection

• **21 sterile compounding pharmacies** inspected in the states of BA, DF, MG, SC, SP, with 10 closures (BA, SC and SP).

Investigation of health violations

13 investigative inspections related to synthetic medicines were carried out

144 measures related to investigation dossiers were published on medicines and 9 on pharmaceutical ingredients

348 open dossiers on medicines with 86 concluded in 2024, and 483 concluded, considering 2024 and previous years

Health Administrative Proceeding

MEDICINES:	**153** Proceedings conducted	**118** responsible parties were charged, totaling 33% of infraction notices	**185** health violations identified
PHARMACEUTICAL INGREDIENTS:	**05** Proceedings conducted	**05** responsible parties were charged, totaling 01% of infraction notices	**05** health violations identified

Price limitation for medicines

2,278 pricing requests received

642 priced medicine presentations referring to 481 active substances

Operating authorization or special authorization

13,158 CANCELLED — operating authorizations were cancelled, since they were related to companies no longer operating

3,142 DEFERRALS — deferrals of operating authorization or special authorization petitions for companies that carry out activities of manufacturing, importing, exporting, distributing, storing, packaging and transporting medicines and pharmaceutical ingredients

316 petitions rejected

Biological Products and Radiopharmaceuticals – Drugs

Regulation of products under health surveillance

Among the approved registrations, **13 drugs (42%)** contain molecules that are new to the country, 4 of which are intended for the treatment of rare diseases, extremely serious illnesses that affect a very small portion of the population.

Approval of the following vaccines:

- *ABRYSVO* (vaccine against respiratory syncytial virus), the second vaccine authorized by Anvisa to prevent respiratory tract infections, but the first capable of immunizing children, from birth to 6 months of age, through active vaccination in pregnant women.

- *SPIKEVAX* and *COMIRNATY*, in updated versions in relation to their composition, in order to include the variant of concern, JN.1, of the virus causing the disease, in accordance with WHO recommendations.

Advanced Therapy Products – Drugs

Regulation of products under health surveillance

3 Advanced Therapy Products were registered:

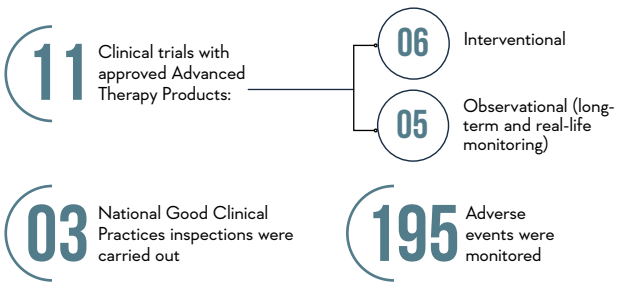
- *Roctavian* – to be used by adult patients with severe hemophilia A;

- *Upstaza* – to be used by pediatric patients with aromatic L-amino acid decarboxylase deficiency (AADC); and

- *Elevidys* – to be used by pediatric patients with Duchenne muscular dystrophy.

All requests for post-registration changes were also evaluated. Advanced Therapy Products, due to their innovative nature, are registered under a Commitment Term for monitoring long-term efficacy and safety results, which must be monitored every year by the Agency.

Clinical trial authorization, modification or cancellation



Approval of exportation and importation of products

- **103 export authorizations** were issued related to ingredients for Advanced Therapy Products.

Tobacco-derived Products

Regularization of products under health surveillance

The review of Electronic Smoking Devices (ESD) regulation was completed, with the enactment of Resolution RDC No. 855/2024, which maintained the sale prohibition of this type of product in the country.

Health inspection

- **24,000 irregular advertisements** for smoking products on the internet were removed through partnership with a social media company.
- **33% increase** in removing advertisements compared to 2023.
- **4,300 irregular advertisements** for smoking products on the internet were removed through the Epinet system.
- **1,200 inspectors** from the National Health Surveillance System were trained, with 6 virtual seminars.

Administrative Health Proceedings

176% increase in proceedings instituted compared to 2023.

Sanitizing Products

Operating authorization or special authorization

Certification of Good Manufacturing Practices

- **9 requests** for national Certification were received, of which: **7 were granted** and **2 were denied**.

Regularization of products under health surveillance

In 2024, Anvisa received **1,113 petitions** for registration of sanitizing products and completed **1,294 petitions**.

Health emergency actions in the state of Rio Grande do Sul

Due to the floods in the state of Rio Grande do Sul in 2024, Anvisa published Resolution RDC No. 865/2024, to temporarily authorize the free sale and donation of 70% ethyl alcohol, in liquid form, duly regulated by Anvisa.

In addition, Resolution RDC No. 878/2024 was published, which simplified the rules for changing the labeling of sanitizing products intended for donation, to make it easier the donation of these products to the affected population.

Actions of the Health Surveillance Notification and Investigation System – VIGIPOS

- **99 reports of adverse events** related to sanitizing products were received.

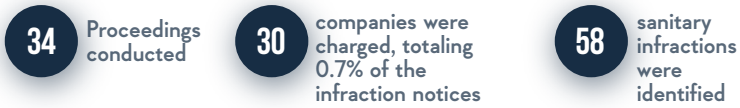
Health inspection

Inspection Program for Hospital Sanitizing Products Companies:

Inspections carried out to verify GMP in companies that manufacture enzymatic detergent, hospital disinfectant for semi-critical items, intermediate-level disinfectant, high-level disinfectant and sterilizer — **05**

Investigation of health violations

Health Administrative Proceedings

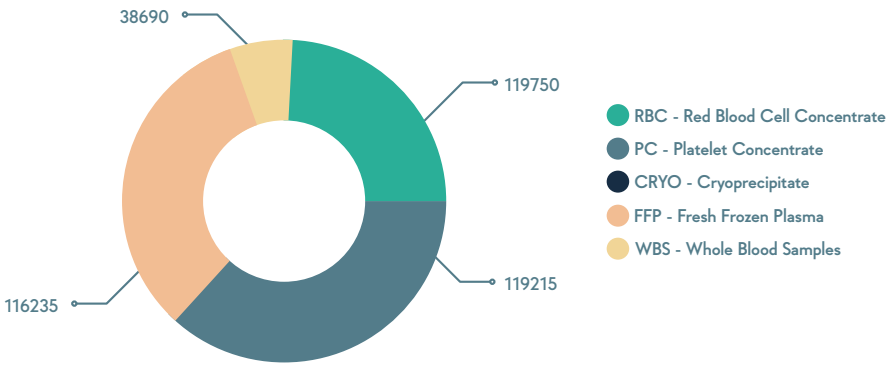


Blood, Tissues, Cells and Organs

Operating authorization or special authorization

- **203 processes** that authorized the flow of approximately 350 thousand blood components were received and analyzed.

Estimated average of products transported between Brazilian states, in processes authorized by Anvisa, in 2024:



Actions of the Health Surveillance Notification and Investigation System – VIGIPOS

HEMOVIGILANCE:

- **18,614** notifications received (78.25% completion rate)
- **5,187** notifications received some kind of treatment
- **960** formal reports were sent to the National Health Surveillance System

BIOVIGILANCE:

- **520** notifications received and analyzed related to risks and adverse events related to human cells, tissues and organs, tracking from donation to the clinical evolution of the recipient and living donor, in transplants, grafts and assisted human reproduction.

75% increase in notifications compared to 2023.

National monitoring networks and programs

- **921 blood, tissue and cell establishments** in the country were inspected by the National Health Surveillance System

- **40% of the blood establishments** evaluated and an estimated coverage of 13.5% of the Assisted Human Reproduction Centers, 11.7% of the tissue banks and 6% of the Cell Processing Centers

Health inspection

Joint inspections with the National Health Surveillance System, representing 97% of the annual program's execution — **35**

Training aimed at professionals in the National Health Surveillance System

Training actions in the field (blood, tissues and cells), in 2024:

TRAINING ACTION	NUMBER OF PARTICIPANTS
CLASSROOM COURSE ON ASSISTED HUMAN REPRODUCTION	44
TWO WEBINARS WERE OFFERED: 1) UPDATE OF THE TISSUE BANK PROFILE FORM, AND 2) INSPECTION GUIDE FOR ASSISTED HUMAN REPRODUCTION CENTERS	245
ONLINE COURSES ON THE AVAVISA PLATFORM	292
COURSE ON GOOD MANUFACTURING PRACTICES FOR BLOOD SERVICES - VIRTUAL CAMPUS OF THE PAN AMERICAN HEALTH ORGANIZATION - PAHO	672

Health Services

Actions of the Health Surveillance Notification and Investigation System – VIGIPOS

Materials published for the National Health Surveillance System:

- **2 Bulletins** on Patient Safety and Quality in Health Services
- **1 Bulletin** (Bulletin No. 29) on Patient Safety and Quality in Health Services
- **24 State reports** with analysis of data on Healthcare-Associated Infections (HAIs) and Microbial Resistance (MR)
- **26 Monthly Reports** on adverse events
- **24 State Reports** with analysis of HAIs and MR data
- **26 Monthly Reports** on adverse events
- **4 Technical Notes** for health services and 1 risk alert
- **3 Technical Reports** on Monitoring incidents/adverse events related to healthcare reported by Citizens in 2024
- **1 Technical Report** regarding monitoring the regularity of reporting incidents/adverse events related to healthcare
- **11 Data Collection** forms and other documents related to HAIs and MR
- **Public panels** to report adverse events
- **Panel** about *Candida auris* outbreak

Health risk in health services and health concerns

Project for Improving the Health Inspection Process in Health Services and Services of Health Concern: this initiative seeks to improve the work of health inspection in Health Services and Services of Health Concern throughout Brazil, promoting the qualification and standardization of the actions carried out. The following results were achieved with this project in 2024:

- 5,111 assessments received with MARP®/OIG.
- 03 new monitoring panels for the Objective Inspection Guidelines (OIG) were created.
- Structuring of an Integrated Panel.

Technical queries

145 technical queries were received about health-related services

1,012 technical queries were received about health services

Investigation of health violations

COMPLAINTS:

96 complaints were received, 48 of which were related to Anvisa's work.

Anvisa received **113 complaints** about health services, a **24% increase** compared to the previous year (91 complaints). The most reported services were hospitals (40 complaints) and beauty care units (15 complaints).

Regulatory System

Update of the regulatory agenda

The new list of regulatory topics on the agenda for 2004 now consists of **171 topics**, arranged in 16 macro-topics.

Enactment of regulatory norms and standards

183 REGULATIONS WERE PUBLISHED:

MACRO THEME	2024
Health products	6
Pharmacopoeia	10
Ports, Airports, Borders and Customs Areas	5
Cross-cutting issues	65
Cosmetics	3
Drugs	30
Food	20
Pesticides	29
Sanitizing products	2
Blood, Tissues, Cells and Organs	0
Management	10
Analytical laboratories	0
Organization and management of the NHSS*	0
Health services	0
Tobacco	3
Pharmaceutical ingredients	0
TOTAL	183

*NHSS (National Health Surveillance System)

Coordination of the National Health Surveillance System

National Health Fund Transfers in 2024

Financing Mechanism	Committed Amount	Allocation
PF-Health Surveillance (states and DF)	R$ 67,472,364.00	Execution of health surveillance actions by states and DF
PF-Health Surveillance (municipalities)	R$ 155,175,312.00	Execution of health surveillance actions by municipalities
PV- Health Surveillance	R$ 27,048,324.00	Incentive for actions and projects to strengthen health surveillance actions
Finlacen-Visa	R$ 23,280,000.00	Execution of actions in public health laboratories for the execution of health surveillance actions
Finlacen – (National Institute for Quality Control in Health)	R$ 2,281,535.00	Transfer of resources from the Ministry of Health to INCSQ/FIOCRUZ for the execution of actions in public health laboratories for the execution of health surveillance actions (Actions not related to the National Health Fund)

TOTAL

R$ 275,257,535.00
Committed Amount

Actions of the Health Surveillance Notification and Investigation System – Vigipos

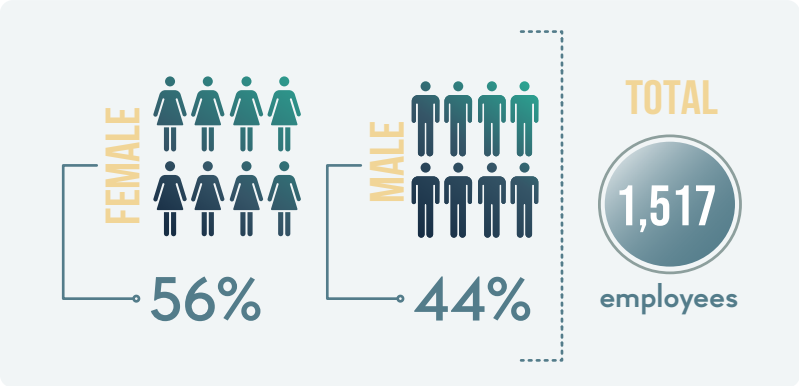
In 2024, Anvisa published **4 alerts** and **1 Safety Report**.

Analysis and judgment of administrative health sanctioning process

COMPLIANCE AND EFFICIENCY IN MANAGEMENT

People Management

Anvisa's workforce



Public contest

In 2024, Anvisa held a national contest for filling 50 positions of specialist in health regulation and surveillance. As a result of the whole hiring process, 49 candidates were effectively hired.

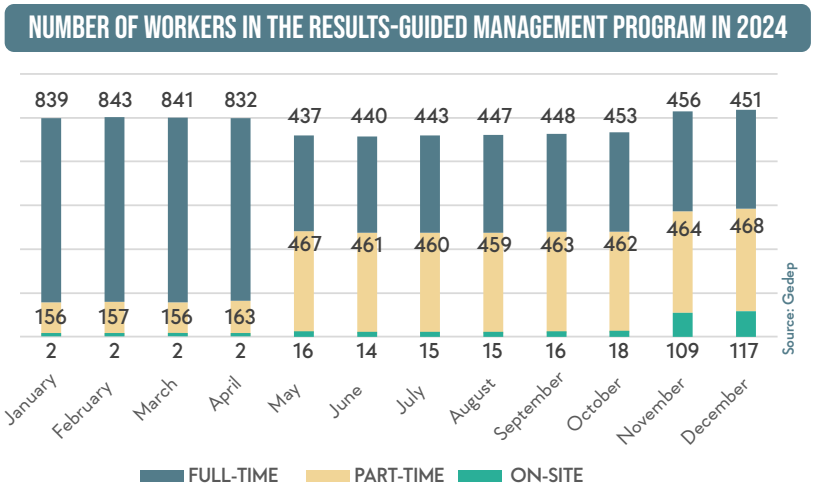
People development

The design of Anvisa's 2024 People Development Plan (PDP) was carried out based specific qualification needs, according to priorities identified by the organizational units.

The People Development Plan Management System, available on the AVA Visa Platform, was improved with the implementation of the Certificate Module, launched in October 2023. With this new tool, it is now possible to better control and monitor the execution of the Plan, as well as make the certificate approval more transparent.

Performance

In 2024, the Results-Guided Management Program introduced new rules, especially regarding some limitations, the full availability of workers, the immediate response of urgent demands, and the accountability regarding the work plan.



The assessment of employee competencies was improved using a dedicated tool for competency management. Technical competencies must be linked to the value chain processes and the worker's behavior must be observable and linked to the institutional process deliveries. In 2024, assessments were carried out on employees working on processes audited by the WHO in order to certify Anvisa as a WLA/GBT.

Information Technology Management

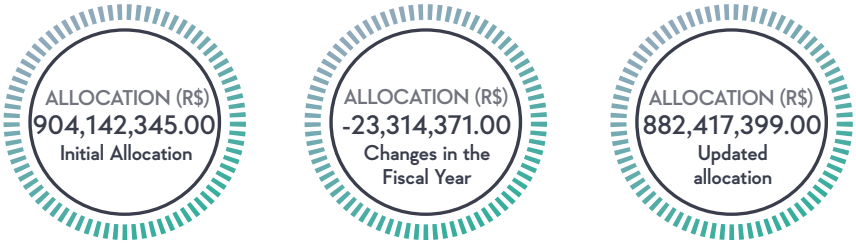
69 services were transformed into nine business areas, linked to the Solicita System and integrated into the assessment tool.

100% of Anvisa services are now available digitally.

- User satisfaction rate – **96.33%**
- Information and Communication Technology (ICT) infrastructure service satisfaction rate – **93.72%**
- Call handling efficiency rate – **94.09%**
- System availability rate of systems installed in the IT infrastructure – **99.68%**
- Network link availability rate – **99.72%**
- Total number of calls to the call center (support levels 1 and 2) – **8,213**

BUDGET

ANVISA BUDGET IN 2024



- **R$ 873 million committed:** 75.06% of Personnel and Social Security expenses
- **R$ 853.5 million in payments made:** R$ 755.6 million in committed expenses and R$ 97.9 million in outstanding payments
- **98.74% of discretionary expenses** executed

Total number of projects executed — **86**

TOTAL AMOUNT EXECUTED: **R$ 49,928,068,04**
(projects from the Annual Procurement Plan (PCA) 2024 + those completed from the PCA 2023 in early 2024)

ANVISA

Brazilian Health Regulatory Agency